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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/339,818	06/25/99	DAVIS	M 038134-50010
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009629
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HM12/0426

EXAMINER

CRANE, L

ART UNIT

PAPER NUMBER

1623

6

DATE MAILED: 04/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/339,818

Applicant(s)
Davis et al.

Examiner
L. E. Crane

Group Art Unit
1623

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

or 1(one)

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 11/08/99 & 12/30/99 (2 IDS's) -----
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-45 ----- is/are pending in the application.
- Of the above claim(s) ----- is/are withdrawn from consideration.
- ☐ Claim(s) ----- is/are allowed.
- ☐ Claim(s) ----- is/are rejected.
- ☐ Claim(s) ----- is/are objected to.
- ☒ Claim(s) 1-45 ----- are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). --4 & 5-- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

- 5 No claims have been cancelled and no preliminary amendments filed as of the date of the instant Office action.

Claims 1-45 remain in the case.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- 10 I. Claims **1-18, 23-34, 37 and 44**, drawn to a cyclodextrin copolymer, a method of making same, pharmaceutical compositions thereof, and a method of treatment wherein the instant compound is administered, classified in Class 536, subclass 103 and Class 514, subclass 58.

- 15 II. Claims **19-23 and 45**, drawn to a composition containing a cyclodextrin copolymer and a second cyclodextrin copolymer which has been oxidized, pharmaceutical compositions thereof, and a method of treatment wherein the instant compound is administered, pharmaceutical compositions thereof, classified in Class 536, subclass 105 and Class 514, subclass 58.
- 20

III. Claims **35**, drawn to a method of making a linear cyclodextrin by reduction of an oxidized cyclodextrin copolymer which lacks a co-monomer "A" which can be reduced, classified in Class 536, subclass 124.

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IV. Claims 36, drawn to a method of making a linear oxidized cyclodextrin copolymer by further oxidation of a partially oxidized cyclodextrin copolymer, classified in Class 536, subclass 124.

5 V. Claims 38-41, drawn to a method of making an oxidized linear copolymer of cyclodextrin by di-iodination of an oxidized cyclodextrin monomer and then copolymerizing same with a co-monomer "A," classified in Class 536, subclass 124.

10 VI. Claims 42-43, drawn to a method of making a crosslinked cyclodextrin copolymer by reaction of a cyclodextrin monomer in the presence of a crosslinking agent, classified in Class 536, subclass 106.

The inventions are distinct, each from the other because of the following reasons:

15 Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the two inventions have different functions, the first invention being directed to a single compound which is not an oxidized cyclodextrin residue, and second invention
20 being directed to a composition containing two compounds one of is an oxidized cyclodextrin residues.

25 Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04

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5 & 808.01). In the instant case the inventions are directed to different methods of making leading to different products, the first invention being directed to the direct synthesis of cyclodextrin polymers, and the second being directed to a method of making a cyclodextrin polymer by reduction of an oxidized cyclodextrin polymer.

10 Inventions **I and IV** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the inventions have different functions, the first invention being directed to a a method of making a non-oxidized cyclodextrin copolymer, and the second invention being directed to a method of making an oxidized cyclodextrin copolymer.

15 Inventions **I and V** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 20 808.01). In the instant case the invention have different modes of operation, the first invention being directed to a method of making a non-oxidized cyclodextrin copolymer, and the second invention being directed to a method of making an oxidized cyclodextrin copolymer via an iodinated oxidized cyclodextrin monomer.

25 Inventions **I and VI** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have

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different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the invention have different functions, the first invention being directed to a method of making a non-crosslinked cyclodextrin copolymer, and the second invention being
5 directed to a method of making a cross-linked cyclodextrin copolymer.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have
10 different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the inventions have different functions, the first invention being directed to a composition containing two cyclodextrin copolymers, and the second invention being directed to a method of making a cyclodextrin copolymer by
15 chemical reduction of an oxidized cyclodextrin copolymer.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have
20 different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the inventions have different functions, the first invention being directed to a binary composition containing two cyclodextrin copolymers, and the second invention being directed to a process for what appears to be the further oxidation of a partially oxidized cyclodextrin copolymer.

25 Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have

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different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the inventions have different functions, the first invention being directed to a binary composition containing two different cyclodextrin copolymers, and the second
5 invention being directed to a method of making an oxidized linear copolymer of cyclodextrin by di-iodination of an oxidized cyclodextrin monomer and then copolymerizing same with a co-monomer "A."

Inventions **II and VI** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use
10 together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the inventions have different functions, the first invention being directed to a binary composition containing two cyclodextrin copolymers, and the second invention
15 being directed to a method of making a cross-linked cyclodextrin copolymer.

Inventions **III and IV** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have
20 different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the inventions have different functions, the first invention being directed to a process for making a cyclodextrin copolymer by reduction of an oxidized cyclodextrin copolymer, and the second invention being directed to a process for
25 making an oxidized linear cyclodextrin copolymer by the further oxidation of a partially oxidized cyclodextrin copolymer.

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Inventions **III and V** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the invention have different functions, the first invention being directed to a method of making a cyclodextrin copolymer by reduction of an oxidized cyclodextrin copolymer, and the second invention being directed to a method of making an oxidized linear copolymer of cyclodextrin by di-iodination of an oxidized cyclodextrin monomer and then copolymerizing same with a co-monomer "A."

Inventions **III and VI** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the invention have different functions, the first invention being directed to a method of making a cyclodextrin copolymer by reduction of an oxidized cyclodextrin copolymer, and the second invention being directed to a method of making a crosslinked cyclodextrin copolymer.

Inventions **IV and V** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the instant invention have different functions, the first invention being directed to a method of making a linear oxidized cyclodextrin copolymer by further oxidation of a

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partially oxidized cyclodextrin copolymer, and the second invention being directed to a method of making an oxidized linear copolymer of cyclodextrin by di-iodination of an oxidized cyclodextrin monomer and then copolymerizing same with a co-monomer "A."

5 Inventions **IV and VI** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04 & 808.01). In the instant case the instant invention have different
10 functions, the first invention being directed to a method of making a linear oxidized cyclodextrin copolymer by further oxidation of a partially oxidized cyclodextrin copolymer, and the second invention being directed to a method of making a method of making a crosslinked cyclodextrin polymer by reaction of a cyclodextrin
15 monomer in the presence of a crosslinking agent.

 Inventions **V and VI** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §§ 806.04
20 & 808.01). In the instant case the instant invention have different functions, the first invention being directed to a method of making an oxidized linear copolymer of cyclodextrin by di-iodination of an oxidized cyclodextrin monomer and then copolymerizing same with a co-monomer "A," and the second invention being directed to a
25 method of making a crosslinked cyclodextrin polymer by reaction of a cyclodextrin monomer in the presence of a crosslinking agent.

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Because these inventions are distinct for the reasons given above and 1) have acquired a separate status in the art as shown by their different classifications, 2) have acquired a separate status in the art because of their recognized divergent subject matter, and 3) the search required for invention I, II and VI is not required for inventions II, IV or V, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Jeffrey A. Lindeman on April 24, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. §1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor if at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. §1.48(b) and by the fee required under 37 C.F.R. §1.17(h).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the

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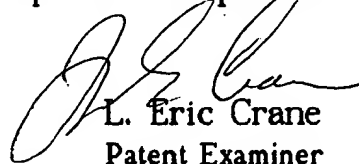
FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592 .

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-308-4639 . The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

10 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1235.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-308-1235 .

15 LECrane:lec
04/24/00


L. Eric Crane
Patent Examiner
Group 1600